REMARKS

Claims 1, 3-5, 9-13, 15, 17-21, 23, 25-27, 29-31, 33, and 35-39 were pending in the application. Claims 4-5 and 27 have been canceled and claims 1 and 23 have been amended. Accordingly, upon entry of the instant response, claims 1, 3, 9-13, 15, 17-21, 23, 25-26, 29-31, 33, and 35-39 will remain pending in the application.

Claims 1 and 23 have been amended to specify a concentration of DTPA from about 0.02 mM to 1mM and a concentration of DEF from about 0.02 mM to 0.5 mM. Support for this amendment can be found throughout the specification and the claims as originally filed. Specifically, support is present, at least, for example, at page 28 (lines 20-24) and page 28 (lines 5-8.

No new matter has been added. The foregoing claim amendments should in no way be construed as an acquiescence to any of the Examiner's rejections and were made solely in the interest of expediting prosecution of the application. Applicants reserve the right to pursue claims covering any subject matter canceled herein in this or a separate application(s).

Acknowledgment of the Examiner's Withdrawal of Certain Rejection

Applicants gratefully acknowledge the Examiner's withdrawal of the previous rejection of claims 1, 3-5, 9-13, 15, 17-20, 23, 25-27, 29-31, 33, and 35-38 under 35 U.S.C. § 112, first paragraph as not being enabled.

Rejection of Claims 21 and 39 Under 35 U.S.C. § 112, First Paragraph

Claims 21 and 39 are rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. Specifically, the Examiner is of the opinion that while the specification is enabling for a composition comprising an antibody formulated with DTPA and DEF, it does not provide enablement for a pharmaceutical composition comprising an antibody formulated with DTPA and DEF. In particular, the Examiner asserts that a composition comprising a high concentration of DEF would not be used by one of ordinary skill in the art for pharmaceutical purposes based on the teachings of U.S. Patent No.: 5,268,165, which discloses that DEF can have undesirable side effects when administered intravenously. The Examiner concludes that since the pending claims read on a composition comprising a high concentration of DEF, the claimed compositions are not suitable for a pharmaceutical purpose.

Applicants respectfully traverse this rejection for the reasons previously made of record. Specifically, Applicants submit that an appropriate concentration of DEF can be determined by one of ordinary skill in the art based on the knowledge available in the art at the time of filing and the teachings set forth in Applicants' specification.

Notwithstanding, to expedite prosecution, independent claims 1 and 23 have been amended to specify particular concentration ranges shown to be effective in the specification, *i.e.*, a concentration of DTPA from about 0.02 mM to 1mM and a concentration of DEF from about 0.02 mM to 0.5 mM, thereby obviating this rejection (see page 28 (lines 5-8 and 20-24) of the specification as originally filed).

Accordingly, in view of the amendments presented herein, the teachings in Applicants' specification, and knowledge available in the art at the time of filing, the presently claimed compositions are fully enabled under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 1, 3-5, 9-10, 12-13, 15, 17-21, 23, 25-27, 29-31, 33 and 35-39 Under 35 U.S.C. § 103

Claims 1, 3-5, 9-10, 12-13, 15, 17-21, 23, 25-27, 29-31, 33 and 35-39 are rejected as being unpatentable over Foster *et al.* (U.S. Patent 5,217,954) in view of Hagiwara *et al.* (U.S. Patent No. 6,165,467), Packer *et al.* (*Methods Enzymol*, 186: 41-42 (1990)) and Akers (*J. Par. Sci. Tech.* 36:222-228 (1982)). The Examiner relies on Foster *et al.* for teaching the use of a pharmaceutical formulation comprising a protein, bFGF, a stabilizing chelator, such as DTPA or EGTA to protect bFGF from oxidation. The Examiner further relies on Foster *et al.* for teaching an agent for tonicity, a preservative or other auxillaries, such as mannitol, glycerol, sodium chloride or Tris. The Examiner relies on Hagiwara *et al.* for teaching a stable human monoclonal antibody preparation and that human monoclonal antibodies have an undesirable property that they easily aggregate and precipitate in a solution state. The Examiner relies on Packer *et al.* for teaching that DEF suppresses iron-dependent generation of OH from H_2O_2. The Examiner relies on Akers for teaching that the use of a combination of antioxidants in the same formulation produces a synergistic effect. The Examiner concludes that it would have been obvious to one of skill in the art that "the use of DTPA and DEF would stabilize a composition comprising a human monoclonal antibody" in view of the cited references.

Applicants respectfully traverse this rejection for the reasons previously made of record.

Notwithstanding, to expedite prosecution, Applicants have amended independent claims 1 and 23 to specify particular concentration ranges for both DTPA and DEF, *i.e.*, a concentration of DTPA from about 0.02 mM to 1mM and a concentration of DEF from about 0.02mM to 0.5 mM. As previously argued, none of the cited references, either alone or in combination, teach or suggest the presently claimed compositions, let alone the particular concentration ranges, as presently claimed.

According, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 1, 3-5, 9-10, 12-13, 15, 17-21, 23, 25-27, 29-31, 33, and 35-39 Under 35 U.S.C. § 103

Claims 1, 3-5, 9-10, 12-13, 15, 17-21, 23, 25-27, 29-31, 33, and 35-39 are rejected as being unpatentable over Kerwin *et al.* (U.S. Patent 5,929,031) in view of Hagiwara *et al.* (U.S. Patent No. 6,165,467), Packer *et al.* (*Methods Enzymol*, 186: 41-42 (1990)) and Akers (*J. Par. Sci. Tech.* 36:222-228 (1982)). The Examiner relies on Kerwin *et al.* for teaching that one or more chelators can be used in a formulation. The Examiner relies on Hagiwara *et al.*, Packer *et al.* and Akers for the reasons discussed above. The Examiner asserts that it would have been obvious to one of skill in the art that "the use of DTPA and DEF would stabilize a composition comprising a human monoclonal antibody" in view of the cited references.

Applicants respectfully traverse this rejection for the reasons previously made of record. Notwithstanding, to expedite prosecution, Applicants have amended independent claims 1 and 23 to specify particular concentration ranges for both DTPA and DEF, *i.e.*, a concentration of DTPA from about 0.02 mM to 1mM and a concentration of DEF from about 0.02mM to 0.5 mM. As previously argued, none of the cited references, either alone or in combination, teach or suggest the presently claimed compositions, let alone the particular concentration ranges, as presently claimed.

According, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

In view of the foregoing, entry of the amendments and remarks herein, reconsideration and withdrawal of all rejections, and allowance of the instant application with all pending claims are respectfully solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

Dated: October 30, 2008

Respectfully submitted,

By_____

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